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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,345	03/20/2001	Derek David Smith	180.0002 0102	2898

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EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/26/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,345

Applicant(s)

SMITH ET AL.

Examiner

Dong Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-26 and 29-53 is/are pending in the application.
- 4a) Of the above claim(s) 34,35 and 48-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26, 29-33, and 36-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21-26 and 29-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention, claims 21-26, and 29-47, in Paper No. 8, filed on 20 June 2002, is acknowledged. The traversal is on the ground(s) that the inventions can be readily evaluated in one search without placing undue burden on the Examiner, all the claims are so interrelated that a search of one group will reveal art to the others, and a separate examination of the groups would require substantial duplication of work on the Office and additional payment on the applicants. This is not found persuasive because any search of the prior art in regard to group I may reveal some information related to the other groups. However, a search is aimed to find references which would render the invention obvious, as well as references directed to anticipation of the invention. Therefore, a search for one group is not adequate as to revealing references anticipating the other groups. Thus, independent searches of relevant literature in different areas of subject matter are required for different groups.

Applicant's species election with traverse of SEQ ID NO:2 in paper No. 9 is acknowledged. The traversal is made to the extent that the requirement will be withdrawn upon the finding of an allowable genus, and any species withdrawn from consideration will be transferred to the elected subject matter unless it is found patentably distinct from the elected or allowed claims. As no generic claim has been indicated to be allowable, this request will be held in abeyance until such time.

The restriction requirement is still deemed proper and is therefore made FINAL.

Currently, claims 21-26, and 29-53 are pending, and claims 21-26, 29-33, and 36-47 are under consideration. Claims 34, 35, and 48-53 are withdrawn from further consideration as being drawn to a non-elected invention, or non-elected species.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Claim 31 is objected to for encompassing a non-elected species, SEQ ID NO:1. The applicant is required to amend the claims to read only upon the elected invention.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-26, 29-33, and 36-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is indefinite and confusing because it is unclear what effect is achieved after “contacting” step. As the method is for *inhibiting* CGRP (vasodilator) binding to the receptor, whereas the active ingredient of the composition used in the method is a vasoactive peptide, does it mean that vasoactive effect would be achieved when using the composition even though the binding of CGRP to its receptors is inhibited ?

Claims 32 and 33 recite the limitation “Z is an antagonist” in line 1. There is insufficient antecedent basis for this limitation in the claims because “Z” is defined in the independent claim 29 as a vasoactive peptide, whereas “an antagonist” in claims 32 and 33 is not a vasoactive peptide as it is neither vasodilator nor vasoconstrictor.

Claim 45 recites the limitation “R1 is a specific structure. There is insufficient antecedent basis for this limitation in the claim because the claim depends from claim 43, in which R1 is another specific structure.

Claim 46 is indefinite and confusing because it is unclear whether the peptide is both “a CGRP antagonist *and* a peptide or polypeptide of at least 15 ...” or the peptide is either one. “The peptide is a CGRP antagonist having at least 15 ...” is suggested.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 21-26, 29-33, and 36-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

With respect to claim 29 and the dependent claims 21-26, 37-45 and 47, the independent claim 29 is directed to a method for inhibiting CGRP binding to its receptors with a composition, and the active ingredient of the composition used in the method is “Z”, a vasoactive peptide. The term “vasoactive peptide” is referred to, in the specification, peptides that are capable of causing vasoconstriction or vasodilatation of blood vessels (page 8, lines 13-14). The specification merely teaches antagonists of CGRP, which are fragments of CGRP, and provides no support that any “vasoactive peptide” can be used in such a method because, by definition, an antagonist is “a substance that tends to nullify the action of another, as a drug that binds to a cell receptor *without eliciting a biological response* (Dorland’s Illustrated Medical Dictionary). Thus, an antagonist of CGRP can be neither a vasoconstrictor nor a vasodilator, therefore, it must *not* be a “vasoactive peptide”. As claim 29 requires “a vasoactive peptide”, and the specification provides no instruction/guidance as to how to make such “a vasoactive peptide”, nor working examples of any vasoactive peptide which can be used in the claimed method, it is not predictable that any vasoactive peptide would inhibit CGRP binding to its receptor. Therefore, undue experimentation is required in order to search for a *vasoactive* peptide that would be within the limitations of the claim. Additionally, it is unclear what is the rationale to use a vasodilator in a method for inhibiting CGRP binding to its receptors, as CGRP is a vasodilator.

Due to the large quantity of experimentation necessary to determine a vasoactive peptide that would be within the limitations of the claim, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention in which an agonist may be used in a method for inhibiting receptor-

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ligand binding, the state of the prior art has not established that any vasoactive peptide would be able to inhibit CGRP binding to its receptor, and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and the claimed invention in its full scope.

With respect to claims 30-33, 36 and 46, the claims are dependent from claim 29, in which Z is defined as a vasoactive peptide. However, "Z" in claims 30-33, 36 and 46 is an antagonist of CGRP. For the reasons addressed above, an antagonist of CGRP can be neither a vasoconstrictor nor a vasodilator, therefore, is not a "*vasoactive peptide*". As the independent claim 29 requires Z to be a "*vasoactive peptide*", claims 30-33, 36 and 46 are not enabled for the claimed method.

Furthermore, even if antagonist of CGRP is used in the claims, enablement would not be commensurate in scope with the claims, which encompass antagonists of any or all CGRP receptors. As CGRP is nonselective, and binds to multiple receptors, these receptors may have other natural ligand(s), functions, and antagonists. The specification merely teaches antagonists of CGRP, which are *fragments of CGRP*, and no other analog species meeting the limitations of the claims were ever identified or particularly described. The skilled artisan would not know how to make a commensurate number of species, based on the single amino acid sequence of human ^{CGRP} SNORF9. It would require undue experimentation in order to make the claimed invention in its full scope.

Conclusion:

No claim is allowed.

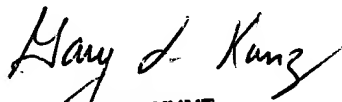
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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800

DJ

9/16/02